

### REMARKS

Claims 1 and 17 are amended herein. Claims 10-13, 15-16 and 18-21 were previously canceled.

Support for the claim amendments is found, for example, at page 14, lines 8-10 of the present specification. No new matter is presented.

Entry of the amendment is respectfully requested and deemed proper after final rejection since the amendments merely clarify that the pharmaceutical preparation is a mixture of components (a) and (b).

Upon entry of the Amendment, claims 1-9, 14, 17 and 22 will be all of the claims pending in the application.

#### **I. Claim Rejection Under 35 U.S.C. § 102**

Claims 1-7, 12-14 and 17 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent 4,525,339 (hereinafter “Behl”).

Claims 12 and 13 are no longer pending since they have been previously canceled.

Applicants respectfully traverse the rejection of claims 1-7, 14 and 17.

The present invention is directed to a composition prepared by mixing a compound recognized by a proton-coupled transporter and a pH-sensitive polymer. Therefore, in the present invention, Eudragit (the pH-sensitive polymer) and  $\beta$ -lactam antibiotics (the compound) are contained in the state of a mixture and thereby impart optimum pH-value to enhance the absorbability of the compound throughout the gastrointestinal tract.

In contrast, Behl describes a pharmaceutical composition comprising  $\beta$ -lactam antibiotics as an active ingredient and an enhancer consisting of a C<sub>2</sub> to C<sub>12</sub> glyceride mixture and adjuvants. Behl merely exemplifies Eudragit as a coating agent.

Behl nowhere discloses the use of a pH-sensitive polymer together with  $\beta$ -lactam antibiotics to enhance cellular uptake. For at least this reason, it is respectfully submitted that Behl does not anticipate the present claims.

Accordingly, Applicants respectfully request withdrawal of the § 102 rejection of claims 1-7, 14 and 17.

## **II. Claim Rejection Under 35 U.S.C. § 103**

Claims 1-9, 12-14, 17 and 22 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Behl in view of U.S. Patent 3,148,124 (hereinafter “Gaunt”).

As previously stated, claims 12 and 13 have been canceled.

Applicants respectfully traverse the rejection of claims 1-9, 14, 17 and 22.

The Examiner states that Behl discloses the combination of  $\beta$ -lactam antibiotics and a pH-sensitive polymer. The Examiner also states that modification of the invention of Behl to substitute glycine for a glycol compound as a release enhancer is obvious in view of Gaunt.

However, as explained above, Behl nowhere mentions mixing Eudragit together with  $\beta$ -lactam antibiotics in the state of a mixture, thereby enhancing the absorbability of  $\beta$ -lactam antibiotics. Applicants submit that the enteric-coated pharmaceutical composition disclosed in Behl only contains a pH-sensitive polymer (Eudragit) in the coating and cannot impart an optimum pH to the entire gastrointestinal tract (intestine), since the coating will dissolve while passing through the intestine, causing the pH value of the intestine to vary by location.

Further, there is no apparent reason to combine Behl and Gaunt with a reasonable expectation of success. Behl is silent about using a compound recognized by a proton-coupled transporter and a pH-sensitive polymer, and Gaunt does not remedy the deficiencies of Behl. Even if Behl and Gaunt were combined, the present invention would not have been achieved

since the substitution of a glycol compound with glycine does not make up for the deficiencies in Behl. Further, the substitution of a glycol compound with glycine in Behl would not lead to the present invention. Thus, neither Behl nor Gaunt teach or suggest the present invention, even if the references were somehow combined.

Moreover, although both Behl and Gaunt refer to the sustained release of drugs, neither mentions adjusting the pH value of the gastrointestinal tract to an optimum level to enhance the cellular uptake of a compound recognized by a proton-coupled transporter. Therefore, a skilled artisan would not arrive at the claimed invention based on the disclosure of Behl and Gaunt, whether taken alone or in combination.

Thus, it is submitted that a *prima facie* case of obviousness has not been established.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the § 103 rejection based on Behl in view of Gaunt.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

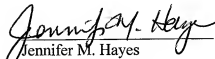
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